Instruction Manual

NeurOptics®

NPi™-100 Pupillometer

NPi-IFU-01 *Revision I* *June 29, 2015*

Symbol	Source/Compliance	Meaning
	Symbol #03-02 IEC 60878	ATTENTION, consult ACCOMPANYING DOCUMENTS.
	Symbol # 5333 IEC 60417 Symbol #02-03 IEC 60878	TYPE BF equipment
	Symbol # 02-02 IEC 60878	TYPE B equipment
	Symbol #5032 IEC 60417 Symbol #01-14 IEC 60878	This symbol indicates the equipment is suitable for alternating current.
	Symbol #5007 IEC 60417 Symbol #01-01 IEC 60878	Indicates ON (Power)
	Symbol #5008 IEC 60417 Symbol #01-02 IEC 60878	Indicates OFF (Power)
		Indicates Intermittent Use
		Indicates Non sterile
		Indicates Keep Dry
		Serial Number
		Model Number
		Lot Number

Table of Contents

Notices *4*
Safety Information *5*
Section 1— Introduction *8*
Section 2 — Unpacking & Setup *9*
Unpacking *9*
Attaching the Headrest *10*
Connecting the Charging Station *11*
Charging the Pupillometer *12*
Section 3 — Using the Device
Powering On and Menu Navigation *14*
Taking a Measurement *16*
Patient ID Number *25*
Printing the Records *26*
Browsing Records to View and Print *28*
Menu Options *29*
Section 4 — Cleaning and Maintenance
Cleaning *31*
Changing the Battery *31*
Printer Maintenance *32*
Appendices
Appendix A—Troubleshooting *33*
Appendix B—Contact & Ordering Information *35*
Appendix C—Phenomena Affecting Pupillary Measurement *36*
Appendix D—Specifications *37*
Accessories and Returned Goods Policy *38*

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NeurOptics™ and NPi™-100 are trademarks of NeurOptics, Inc.
Seiko™ is a trademark of Seiko Instruments, Inc.

EMC Notice

NeurOptics® NPi™-100 Pupillometer (device) generates, uses, and can radiate radio frequency energy. If not set up and used in accordance with the instructions in this manual, electromagnetic interference may result. The equipment has been tested and found to comply with the limits set forth in EN60601-1-2 for Medical Products. These limits provide reasonable protection against electromagnetic interference when operated in the intended use environments (e.g. hospitals, research laboratories) described in this manual.

MRI Notice

This device contains components whose operation can be affected by intense electromagnetic fields. Do not operate the device in a MRI environment or in the vicinity of high-frequency surgical diathermy equipment, defibrillators, or short-wave therapy equipment. Electromagnetic interference could disrupt the operation of the device.

Intended Use Notice

The NeurOptics® Pupillometer is a handheld optical scanner which captures and analyzes a digital video of the human pupil responding to light stimulation. **It should only be operated by properly trained personnel.**

The results obtained from the Pupillometer scans are used for information only and are not to be used for any diagnostic process.

Regulatory Notice

Federal law restricts the sale of this device except by or on order of a physician.

Classification

Type of Equipment: Medical Equipment, Class 1 886.1700

Trade names:

NeurOptics® NPi™-100 Pupillometer

Manufactured by:

NeurOptics, Inc
18101 Von Karman Avenue, Suite 1940
Irvine, CA 92612
USA

If you have a question regarding this product, please contact NeurOptics at one of the numbers given in Appendix B.

Indications for use

Used for measuring a dilated or non-dilated pupil.

Contraindications

Avoid use when the orbit structure is damaged or surrounding soft tissue has an open lesion or edema.

Safety Information

Please review the following safety information prior to operating the device.

Read the Operating Instructions fully before attempting to use the Pupillometer. Attempting to operate the device without fully understanding its features and functions may result in unsafe operating conditions and/or inaccurate results.

If you have a question regarding the installation, set up, operation, or maintenance of the device, contact NeurOptics as shown in Appendix B.

Terms

WARNINGS	Identify conditions or practices that could result in serious adverse reactions or potential safety hazards.
CAUTIONS	Identify conditions or practices that could result in damage to the device or other equipment.
NOTES	Identify supplemental information to help you better understand how the device works.

Warnings

Warnings and Cautions appear throughout this manual where they are relevant. The Warnings and Cautions listed here apply generally any time you operate the device.

Use of the Pupillometer - The Pupillometer is intended for use by trained clinical personnel, under the direction of a qualified physician.

If a problem is recognized while operating the device, the device must be removed from use and referred to qualified personnel for servicing. Using an inoperative device may result in inaccurate readings.

Electric shock hazard - Do not open the device or the charging station. There are no user serviceable parts. Refer *all* servicing to a NeurOptics authorized service technician. Opening up the device will void the warranty.

Use only the specified lithium ion rechargeable battery (P/N -BATPUP-01) in the Pupillometer.

Use only power adapters which are shipped with the NeurOptics Pupillometer system. Using unauthorized parts will void the warranty.

Use only the NeurOptics charging station for charging Pupillometer batteries.

Risk of fire or chemical burn - The battery used in this device may present a risk of fire or chemical burn if mistreated. Do not disassemble, heat above 100 degrees C, incinerate, or dispose of in fire.

Risk of fire or explosion - Replace the Pupillometer battery with battery specified in Appendix B. Use of another battery may present a risk of fire or explosion. Dispose of battery promptly. Keep away from children.

Cautions

The following cautions apply any time you work with the device.

A battery that is fully drained (i.e. void of any charge) may cause damage to the device and should be replaced.

Be careful when removing the headrest to ensure that you do not damage the lens. Make sure that you do not “rotate” the lens when fitting or removing the headrest.

The following cautions apply when cleaning the device or when sterilizing device accessories.

The internal components of the Pupillometer are not compatible with sterilization techniques, such as ETO, Steam Sterilization, Heat Sterilization and Gamma.

DO NOT submerge the device or pour cleaning liquids over or into the device.

DO NOT use acetone to clean any surface of the pupillometer or charging station.

Section 1 — Introduction

The NeurOptics® NPi™-100 Pupillometer is a handheld optical scanner. It stimulates the eye with a flash of light and captures and analyzes a rapid sequence of digital images to obtain a temporal measurement of the diameter of a human pupil. The system acquires images using a self-contained infrared illumination source and a digital video camera. It analyzes the captured image data and displays a summary of the measurement in the LCD window. Data may also be printed out on an optional thermal printer.

The NeurOptics® NPi™-100 Pupillometer uses a menu driven graphical user interface (GUI), with a color LCD screen for data display. A keypad completes the user interface and enables manual entry of individual subject identification (ID) numbers and other information.

The Pupillometer is powered by a 3.7 volt rechargeable lithium ion battery.

Pupillary data sampled at 32fps and for a total duration of 2.7 seconds is used in the calculation of a number of different pupillary variables that are displayed at the end of each single measurement.

The NeurOptics® system includes a Pupillometer, a rechargeable battery, and a charging station and power supply. The Pupillometer must also be used with the headrest. Options are listed in Appendix B and can be ordered separately.

Features

- The NeurOptics® NPi™-100 Pupillometer has been designed to be a lightweight device with a small footprint.
- The device has the capacity to store approximately 3,000 measurements.
- The optional Seiko™ thermal printer enables hard copy printing of results.

Section 2 — Unpacking and Setup

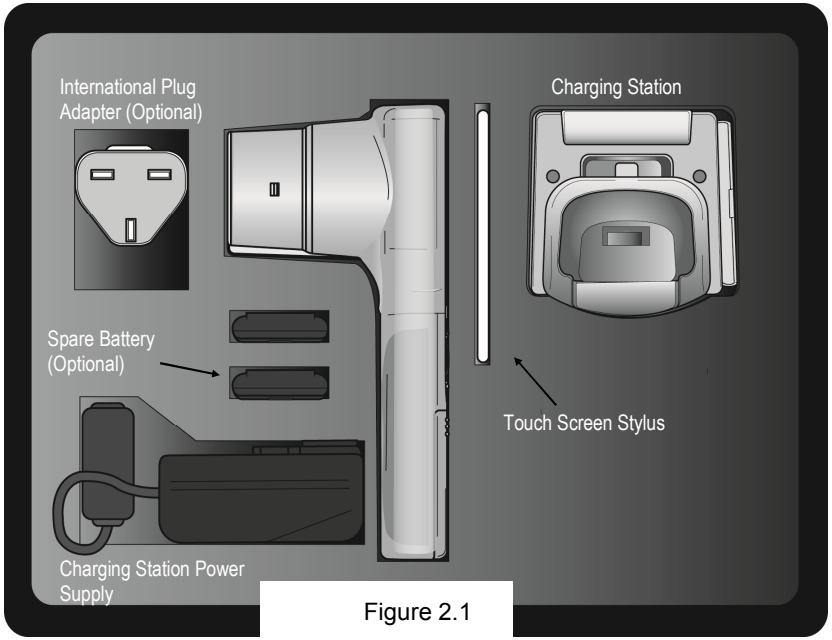


Figure 2.1

Unpacking

The NeurOptics® system is housed in a protective hard shell case. Included with your system are:

- The Pupillometer
- Lithium ion battery
- Medical grade power supply for the charging station
- The charging station.
- Touch Screen Stylus

Please check the contents of your case (Figure 2.1) when delivered. If anything is damaged or missing please contact NeurOptics at once at +1 949-250-9792. **DO NOT ATTEMPT TO USE A DAMAGED DEVICE**! The Pupillometer may not function correctly if it has been damaged or tampered with.

Attaching the Headrest

The Pupillometer should not be used without the headrest positioned correctly.

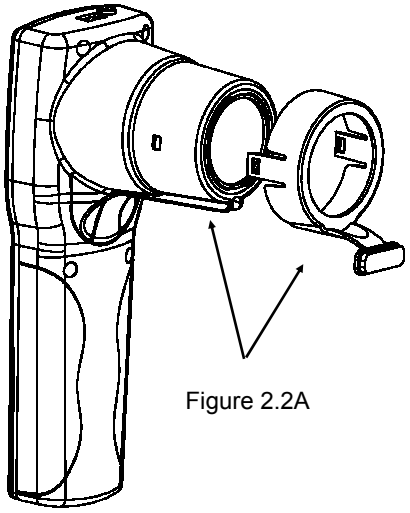


Figure 2.2A

It is very important that the headrest be correctly fitted. It helps the correct and firm positioning of the Pupillometer in front of the patient's eye. The device will not be able to scan the eye unless the headrest is attached.

The headrest has a tab in the rim, which fits into the indentation in the lens shield of the Pupillometer. Position the tab in the headrest rim into the indent in the lens shield and press into place. The tabs on either side of the lens shield should also snap into the holes on either side of the headrest.

The headrest fits onto the Pupillometer as shown in Figure 2.2A. The headrest is disposable and it should be changed for each patient for hygienic reasons. To order additional headrests, call the number given in Appendix B. and request part number NPi100-HR.

WARNING

Pupil measurements are not enabled when the headrest is not properly fitted onto the Pupillometer.

CAUTION

Do not touch the lens when fitting or removing the headrest. Damage to the lens may result.

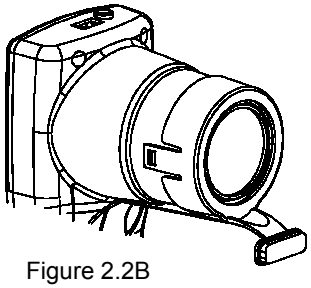


Figure 2.2B

When the headrest is correctly positioned, the contour of the headrest should be aligned as shown in Figure 2.2B.

Connecting the Charging Station

Connect the NeurOptics medical grade 6-volt power supply included with your system to the center plug in the charging station as shown in Figure 2.3. Connect the power supply to a suitable AC outlet. After a second you should see a blue LED illuminate on the plug of the power supply and a green LED on the front of the charging station. The other 2 plugs in the back of the charging station are for NeurOptics use only.

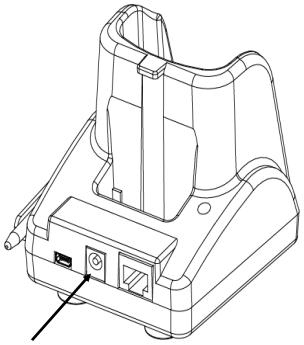


Figure 2.3

WARNING

Use ONLY NeurOptics Part number NEUR-PWR1-01 power supply with the NeurOptics® Charging Station. The Pupillometer may be damaged if an incorrect power supply is used.

Charging the Pupillometer

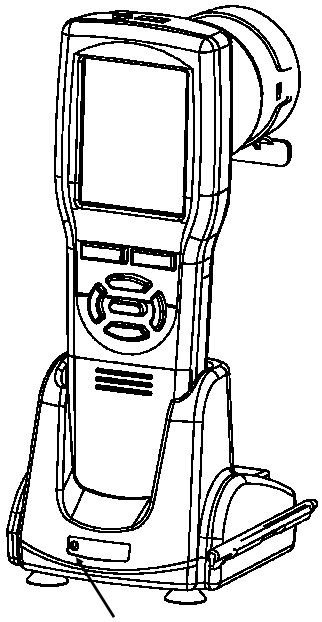


Figure 2.4

Install the Pupillometer battery into the Pupillometer (see Section 4). The battery must be fully charged prior to first use. This may take up to four hours. The battery status is indicated by the battery icon on the LCD screen of the device.

The arrow in Figure 2.4 points to the green LED on the front of the charging station which, when lit, indicates that the charging station is powered up correctly.

When placing the Pupillometer into the charging station, the Pupillometer should be inserted at a 90-degree angle straight down until a click is heard. The battery icon in the LCD screen will show a blue lightning bolt symbol indicating that the device is properly connected to the charging station.

When removing the Pupillometer from the charging station, do not pull straight up. First, *rotate the device forward* and once it releases *then* pull it up. (See Figure 2.6).

When the Pupillometer is properly positioned in the charging station for charging, the headrest on the Pupillometer should be facing the rear of the charging station with the keypad and screen towards the front as shown in Figure 2.4. This will orient the terminals on the Pupillometer with the terminals in the base of the charging station and enable a correct electrical connection.

The arrow indicates the charging status light for the Pupillometer.

Figure 2.5

Note

IF THE LIGHTNING BOLT superimposed over the battery icon IS NOT VISIBLE while placed in the charging station, THE DEVICE IS NOT CHARGING. (Figure 2.5)

CAUTION

Do not try to pull the device up out of the charging station without first rotating it forward to release.

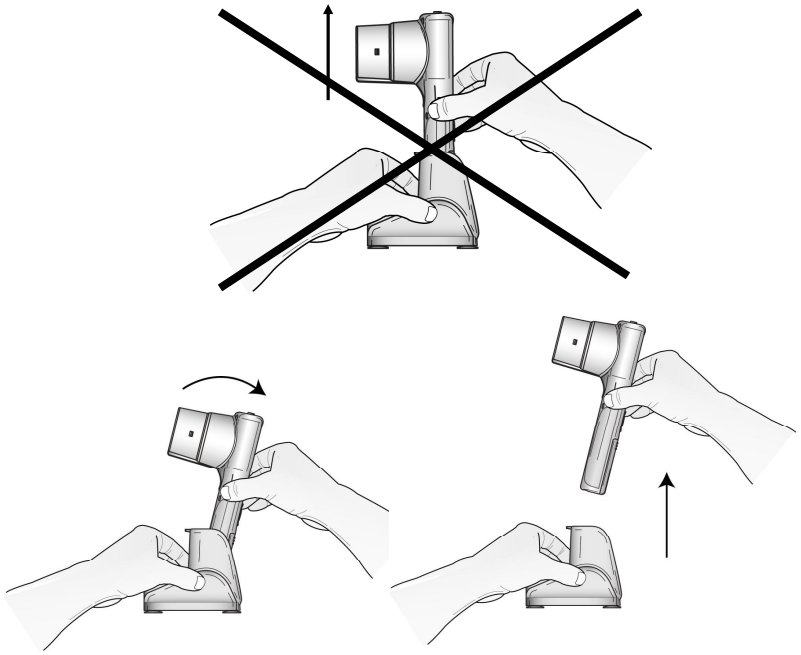


Figure 2.6

Section 3 - Using the Device

Powering On the Device and Menu Navigation

Insert the battery and make sure it is fully charged before first usage (refer to Section 4). After the system has booted up (by holding the up arrow key down for a few seconds or placing the device into the charging station), which takes a

dew seconds, the default measurement screen will display as shown in Figure 3.2A.

The main menu bar is displayed at the bottom of the default measurement screen and can be activated (Figure 3.2B) by pressing the down arrow ▼ of the directional keypad of the Pupillometer (Figure 3.1). Each icon in the menu bar corresponds to a different function of the Pupillometer. Notice that the key in the center of the keypad, labeled with a solid circle ● , is the SELECT key.

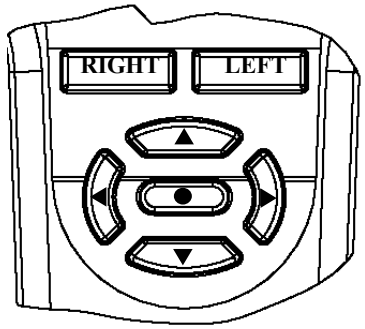


Figure 3.1

Note

In order to conserve battery power while outside of the charging station, the Pupillometer will go into "sleep" mode after 3 minutes of inactivity. The device will turn itself off after one hour of inactivity.

When in *sleep* mode outside of the charging station, the Pupillometer LCD backlight will be turned off and can be turned back on with a quick press-and-release of any button of the keypad. If the device is *turned off*, it can be turned back on by pressing and holding the up arrow key on the keypad for 3 seconds

To activate the main menu bar, press the down arrow key ▼

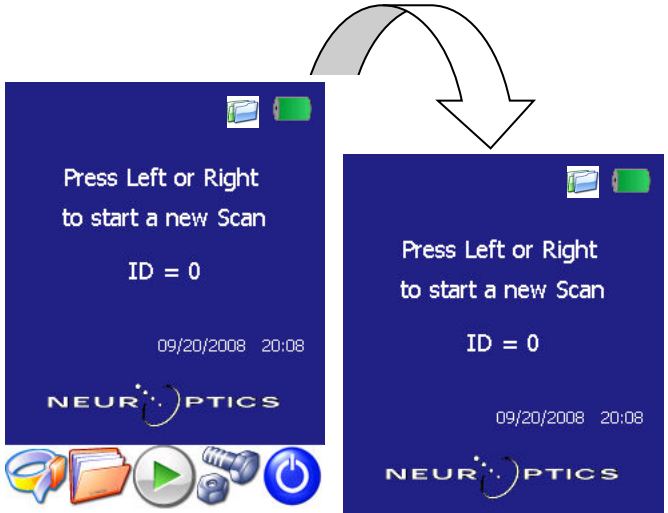


Figure 3.2A

Figure 3.2B

To exit the menu bar or any submenu (see the next Section for an explanation and list of submenus) and return to the default measurement screen, press the LEFT or RIGHT key on the keypad.

Once the menu bar has been activated by pressing the down arrow, the icon which is highlighted will have a square frame drawn around it. To highlight a different icon, use the left or right arrow keys on the keypad ◄ ► Once the desired icon has been highlighted, press the SELECT key on the keypad to select that icon.

or placing the device into the charging station. Every time the device is turned on, the four white LEDs will flash briefly.

Taking a Measurement

Patient and environment preparation

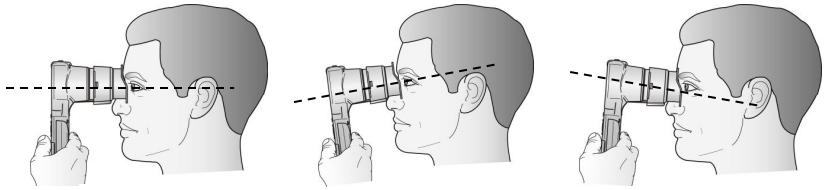
Below are a few general instructions:

- If the patient is awake and conscious, ask the patient to keep his head straight and both eyes wide open during both targeting and measurement. Instruct the patient to look straight or to focus, with the eye that is not being tested, on an object in the distance.
- When the patient is not awake or in those cases when targeting becomes a problem, it may be necessary to manually and gently hold the patient's eyelid open.
- The operator should position the instrument at a right angle to the patient's axis of vision and any tilting of the instrument should be minimized (Figure 3.3A).
- It may be helpful for the operator to be at the same level as the patient when performing the scan to minimize tilting. If necessary (and feasible), both patient and operator can sit down facing each other during targeting and measurement.

Results Screen

Note

The results of a measurement of the right pupil are reported in the left column and the results of the left pupil in the right column (Figure 3.5A). This is to maintain consistency with the apparent orientation of the patient's two eyes with respect to the operator's point of view. The results of the two eyes are also differentiated by color, green for the right pupil and yellow for the left pupil. A helpful mnemonic rule to associate "right" with "green" is to remember that both words have the letter 'R'.

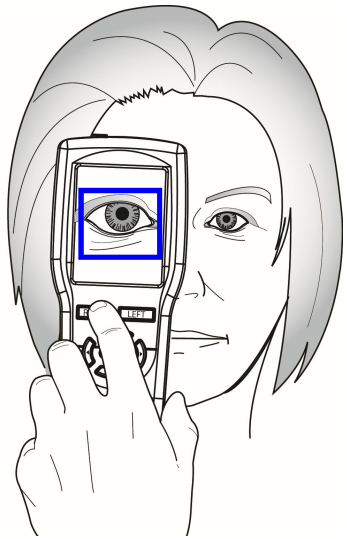


Good alignment: tilting is minimized.

Poor alignment: device is tilted.

Poor alignment: device is tilted.

Figure 3.3A



Pressing the RIGHT or LEFT button activates the Targeting phase (see next Section). Press and hold down the RIGHT or LEFT button and keep the Pupillometer snugly up to the patient's eye. During this phase, a video image of the eye is displayed in the LCD window. The patient's pupil must be centered within the field of view (within the blue rectangle). (Figure 3.3B).

Figure 3.3B

Initiating the SCAN

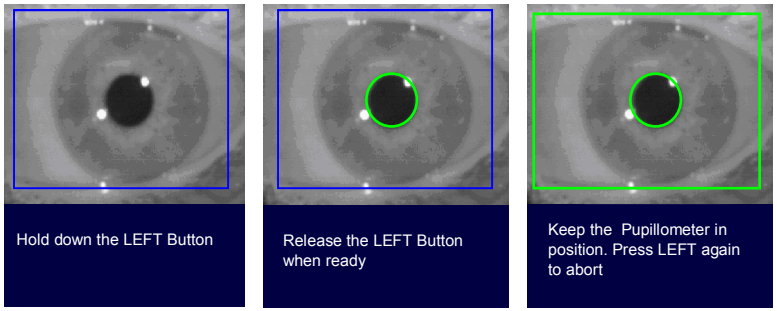
A measurement can only be taken from the default measurement screen (Figure 3.2A). To return to the default measurement screen from any other window, menu, or submenu, press RIGHT or LEFT on the keypad. To initiate a new scan from the measurement screen, press RIGHT or LEFT on the keypad, depending on which eye is going to be measured.

Note

The RIGHT or LEFT keys will initiate a scan from the default measurement screen only (Figure 3.2A). If the RIGHT or LEFT key is pressed during any other system mode, the Pupillometer will not initiate a new scan but instead will return to the default measurement screen. This is similar to the ESC [escape] key on a computer.

Pupil measurement

A pupil measurement is divided into three distinct phases (Figure 3.4).


Hold down the LEFT Button
Release the LEFT Button when ready
Keep the Pupillometer in position. Press LEFT again to abort

Phase 1 - Either the RIGHT or the LEFT scan button is pressed. Video is enabled and displayed in the Pupillometer LCD screen. The user is required to hold the RIGHT or LEFT scan button down, position the Pupillometer on the patient's eye and center the patient's pupil in the center of the blue rectangle in the field of view. This is called the **Targeting phase**.

Phase 2 - The Pupillometer automatically detects the pupil. The pupil is marked with a green circle drawn around its perimeter. The operator can now release the button when ready to initiate the actual measurement (i.e., once the green circle appears around the pupil). This is called the **Ready phase**.

Phase 3 - When the RIGHT or LEFT scan button is released, the actual pupil recording is initiated. Keep the Pupillometer firmly on the patient's eye for the entire duration of the recording which lasts 2.7 seconds. Do not move or remove the device during this period of time. If you need to abort the measurement, then press the RIGHT or LEFT button again. Once the measurement is complete, the results will appear on the LCD screen. At this point the device can be removed from the eye. This is called the **Measurement phase**.

Figure 3.4

WARNING

If no pupil is found and detected in the field of view during the Targeting Phase, the Pupillometer will not transition to the next (Ready) Phase and the pupil scan cannot be initiated.

The Targeting and Measurement phases take a few seconds (depending on the duration of the Targeting phase), during which time the patient's eye should be wide open, with no blinking. While the measurement is being recorded, hold the Pupillometer as still as possible, minimizing any tilting until the measurement results are displayed on the screen (Refer to Figure 3.3A).

WARNING

If the green pupil boundary circle is NOT centered on the pupil perimeter during the Targeting phase, do not release the scan (RIGHT or LEFT) button.

At the end of the Measurement phase the scan results will display almost immediately as shown in Figure 3.5A. Press the Select button to change to the graph view as shown in Figure 3.5B. If the patient's eyelid is closed or droopy, the patient should be instructed to open his/her eyes as widely as possible or the operator can use his/her fingers to keep the eyelid open. If the patient is wearing heavy eye makeup which may interfere with the scan, hold the eyelid open as widely as possible.

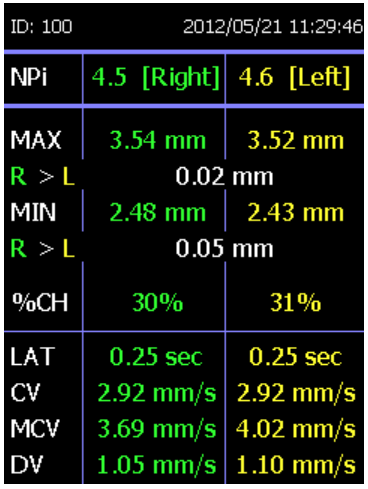


Figure 3.5A

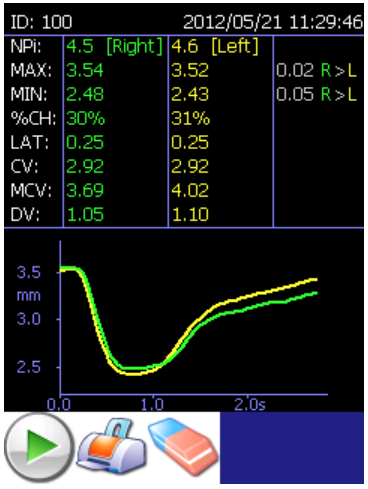


Figure 3.5B

If the initial part of the measurement was affected by a tracking problem (e.g., blinks) then measurement results are all displayed in red font on the results screen. *In this case, the measurement results are not valid and should not be relied upon and the measurement should be repeated.* If pupil data can be recovered by the analysis algorithm, then measurement results can still be evaluated and they are not displayed in red. In this case the blink will be reported in the graph with a darker line connecting the two extremities of the blink (Figure 3.5C).

The results screen reports a number of pupillary variables:

- **ID,** the identification code of the patient measured (for example 0 in Figure 3.5A); which eye was measured and the date and time of the measurement.
- **NPi™** is the Neurological Pupil index™ and it measures the level of the pupillary light reaction per the NeurOptics® NPi™ algorithm. The value ranges between 0 and 5 and can be trended.

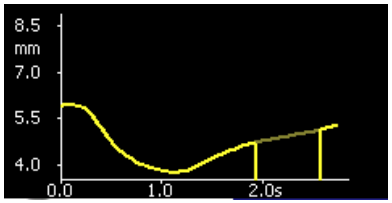


Figure 3.5C

1. An NPi™ value equal to or above 3 indicates that the intensity of the pupil response falls within the range of a NeurOptics® “normal” population. Within this range in a given patient, NPi™ values closer to 3 are weaker than NPi™ values closer to 5. Look for trends up or down.

2. An NPi™ value below 3 indicates weaker responses compared to the

NeurOptics® "normal" population.

3. If dashes are reported "---", the pupil response did not follow typical light reflex behavior as defined by the NeurOptics® algorithm (and all the other variables are also reported with dashes). This might be due to a nonresponsive pupil, or a response smaller than the optical capacity of the device or other measurement factors. The operator should repeat the measurement and check the presence of a response by zooming in on the pupil profile by pressing the SELECT key ● on the keypad. Zooming is recommended for very small pupils whose response may be difficult to see on the main results screen. If a blink occurred anywhere during the measurement, NPi is reported as "*blnk*".

- **MAX** represents the maximum pupil diameter before constriction (MAX=3.54 mm in this example, right pupil). **MIN** is the pupil diameter at the peak of constriction (MIN=2.48 mm in this example). Both are reported in millimeters. The variable **%CH** is the percent of the change (MAX—MIN)/MAX as a percent.

- **LAT** is the **latency** and it represents the time of the onset of the constriction. It is given in **seconds** (for example 0.25 seconds in Figure 3.5A).

- **CV** and **MCV** are the **average** and the **maximum constriction velocity** and they are given in **millimeters/second**, respectively (in the example, **2.92 mm/s and 3.69 mm/s**). Both velocities, **CV** and **MCV**, refer to the constricting movement of the pupil diameter responding to the flash of light.

- **DV** is the **dilation velocity** (given in **millimeters/second**) and represents the average pupillary velocity, when, after having reached the peak of the constriction, the pupil tends to recover and to dilate back to its initial resting size (**1.05 mm/s** in the example, Figure 3.5A).

Note

If a variable could not be measured, for example if no pupillary movement is detected after light stimulus, then its value is reported with dashes (---). When in doubt, repeat measurement and watch the video playback. Correlate findings with a proper neuro assessment and in the context of any drugs that have been administered. to the patient.

Pairing of measurements

Two consecutive measurements, taken on two different pupils (left and right) within a period of 1 minute apart are paired, which means that they are displayed together in the same results screens as indicated in Figure 3.6. A third column, representing the difference between the two measurements, is added. Pairing is a display feature intended to facilitate the comparisons between the two eyes. Pairing is the default and preferred setting. To disable pairing, refer to the instructions for Settings on page 29.

Note the two pupil graphs at the bottom of the results screen that are overlapped on the same plot in order to facilitate comparisons. Remember that the green plot is for the right pupil and the yellow plot is for the left pupil.

The pairing feature is indicated with the “double folders” icon on the top right corner of the default measurement screen to the left of the battery icon.

Figure 3.6

Note

Measurements <u>can be taken in any order</u>, left-right or right-left but they must be taken less than one minute apart and they must both be valid measurements. The date and time of the pair corresponds to the latest measurement in the pair. The text color of date and time and ID indicates which was the latest pupil measured in the pair — in the example above (Figure 3.6), it was the left pupil and consequently the ID and date and time are displayed in yellow at the top of the screen.

Patient Identification (ID) number

To enable recall of patient data, a **Patient ID** number may be entered before initiating a scan. Assigning a Patient ID number is optional. If not entered, the new measurement will be associated with the latest and current ID which is always indicated on the default measurement screen (Figure 3.2A). The Pupillometer will list the last 100 ID's entered. To assign a new ID number or to change it, select the ID bracelet icon on the main menu bar in the default measurement screen:

The short menu bar at the bottom of the results page can be activated with a press of the down arrow key ▼ . Three options are available:

to PLAY the video of the latest measurement.

to PRINT the current record (see section below).

to DELETE the current record.

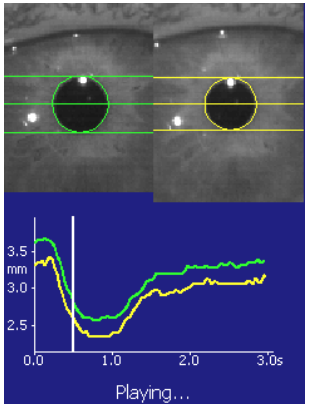


Figure 3.7

In the case of paired measurements, the corresponding video will play the two pupils in sync and side by side in the same window (Figure 3.7). This dual video is aligned such that the center of the two pupils is at the same height. The extent of the two pupil diameters is indicated by horizontal lines of different colors and they serve to better visualize differences in size between the two pupils.

The video can be stopped (SELECT key on the keypad) and advanced one frame forward or backward using the right or left arrow keys on the keypad.

A vertical bar will scroll from left to right over the two pupil graphs as the dual video progresses in time (see the plot at the bottom, Figure 3.7).

To enter a new ID, press SELECT on the first menu

Only the last measurement's video can be played back. Once the device has been turned off, the last video is not accessible.

option “New ID” (Figure 3.8) and the complete keyboard will be displayed in the screen (Figure 3.9). Any combination of lower and upper case letters and numbers can be used to create a new ID, up to a maximum of 9 digits or letters. Numbers or letters can be selected through the touch screen interface by pressing the corresponding character or number displayed on the screen. Also characters can be input by navigating over the keyboard using the directional keypad and pressing SELECT (on the Pupillometer keypad) to select the current character or number or symbol. In order to shift between lower and upper case letters and numbers, select the “Shift” key (Figure 3.9). *You must press the “Enter” key on the displayed keyboard once the new ID entry is completed*. The results of the patient’s next scans will be stored under this ID number.

Figure 3.8

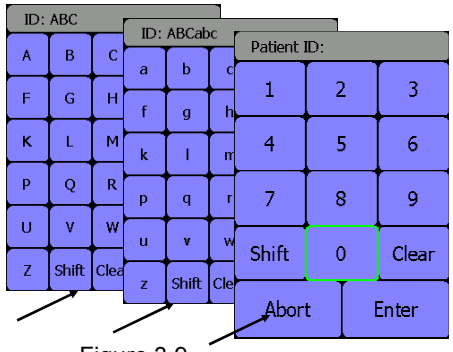


Figure 3.9

In case other ID numbers are present in the Pupillometer database stored in memory, these will be listed in the same window (for example in Figure 3.8 see IDs 3, 2 and 1). These IDs can be selected by using the directional keypad (arrow up and arrow down) and then pressing SELECT. This function is useful for immediately re-entering a Patient ID already in memory without the necessity of typing it again.

Printing the Records

Attach the power supply to the printer as shown in Figure 3.10. Turn the printer on and the green light will illuminate.

The patient record currently displayed in the results window can be printed by activating the short menu bar at the bottom of the results page (Figure 3.5) with a press of the down arrow key and then selecting the printer icon.

The range of the IrDA transceiver on the Pupillometer is less than one meter. If the Pupillometer is too far away from the printer, not pointed directly at the printer IR window (see Figure 3.11), or if the printer is not turned on, the error message “Print Failed” will be reported in the LCD of the Pupillometer. If the connection is successful and printing has been completed, a “Print Done”

Figure 3.10

message will appear. It will take only few seconds for a single record to print.

During printing, hold the Pupillometer directly in front of the IR (infrared) window of the thermal printer as shown in Figure 3.11. A wireless connection is established with the printer through direct line of sight. The printout is a text summary of the results page. For printing a measurement other than the last measurement taken, refer to the “Browsing Records to View and Print” section.

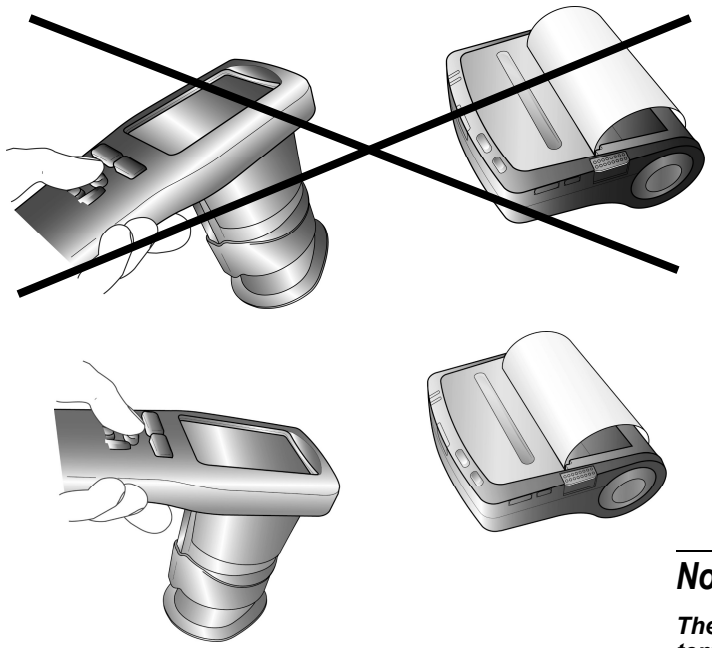


Figure 3.11

Note

The system will only print a record when data is displayed on the screen (i.e. after a measurement or when "browsing records").

Consult the printer's instruction manual for specific printer operation instructions.

Menu Options

The main menu bar provides a few more functions:

Browsing records to view and print

Previous measurements can be browsed, retrieved and printed by selecting the folder icon in the main menu from the default measurement screen:

In the Browse catalog window (Figure 3.12) it is possible to select which patient to browse (and print). One option available is to browse all records in memory (“All Records”, Figure 3.12) or a specific patient ID number (“Enter ID”, Figure 3.12). For convenience, the Browse catalog lists the 100 most recent patient ID numbers so that the operator can select directly from the catalog without having to re-enter the Patient ID using option “Enter Patient ID”.

Figure 3.12

All records corresponding to the ID specified in the Browse catalog window will be displayed (as in Figure 3.5). Review of each single record is possible using the right and left arrow keys in the directional keypad (Figure 3.1). Each time a record is displayed in the LCD, the record can be printed by selecting the printer icon on the menu bar located at the bottom of the record display.

This window allows the user to:

— Enable (*w*) or disable (*wo*) the printout of the pupil graph. Press the SELECT key to toggle between these two options; if print of pupil graph is disabled (*wo*), then, only the pupil variables will be printed and printing is faster.

— Test the white visible LEDs. When this option is selected, the four white LEDs are briefly flashed. This test should be repeated regularly to ensure that the pupil light stimulation is fully functional. The four white LEDs are also flashed every time the device is turned on (see page 16).

— Dim the LCD backlight illumination. Press the SELECT key to toggle between different backlight illumination levels and then press RIGHT or LEFT to save and exit.

— Change the Pupillometer date and time. If selected, the numeric keyboard will be displayed on the LCD (Figure 3.9). The current date and time will be reported on the top of the keyboard. These setting can be changed by pressing “Clear” and re-entering the correct settings using the directional keypad of the Pupillometer (Figure 3.1). Select “Enter” on the LCD to save the new settings for the date and repeat the same steps for setting the time (whose keyboard is automatically displayed after date has been set). Note that time is in 24-hour format (i.e., from 00:00 to 23:59). Daylight saving time needs to be set manually.

— Enable or disable the pairing display feature. When pairing is enabled, this icon is displayed in the default measurement screen to the left of the battery icon.

Warning

If one of the four white LEDs stops working, the device should not be used as this will affect measurement results. Contact NeurOptics Customer Service immediately for assistance.

Play Video

Video of the latest measurement (either a single one or a pair, in case pairing was enabled and two last measurements could be paired) can be played also from the default measurement screen selecting this icon in the main menu bar.

Power Off

This icon is for turning the device off. The Pupillometer will ask you for confirmation before performing this operation. The device can be powered back on by pressing the up arrow key for 3 continuous seconds or by placing the device into the charging station.

Section 4 - Cleaning & Maintenance

Cleaning

The NeurOptics® Pupillometer and charging station are non sterile products.

DO NOT attempt to sterilize any part of the NeurOptics® Pupillometer system, as sterilization may damage the device.

To clean the surfaces of the NeurOptics® Pupillometer or charging station, use a soft, lint-free wipe with a quaternary disinfectant or isopropyl alcohol (IPA) 50% IPA/50% water.

DO NOT immerse or drip liquids on to the Pupillometer or charging station.

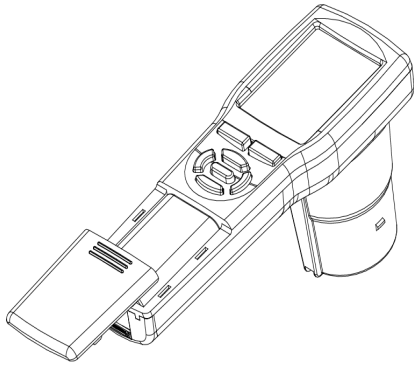
DO NOT use acetone to clean any surface of the Pupillometer or charging station.

The LCD window should be cleaned using a soft, lint-free wipe and IPA.

Clean the lens with lens cleaning solution and a lint free cloth.

Changing the Battery

To maximize available battery reserve, it is recommended that the Pupillometer be stored in the connected charging station when not in use.



To change the battery, open the housing compartment by pressing down to release the catch and pulling outward. (Figure 4.1) Insert the battery with the terminals as indicated on the label in the battery compartment.

Figure 4.1

A battery status icon is visible on the main LCD screen which changes shape and color as the battery is depleted.

When the Pupillometer has a full charge, the battery status icon is shown as fully green:

As the charge decreases, the area inside the icon reduces and will eventually change into yellow:

A severely depleted battery is displayed by the level indicator being reduced to the very bottom and the color changes to red . A text message will appear which reads “Please charge device.”

Place the Pupillometer into the Charging Station to charge the battery. During charging, a lightning bolt is overlaid on a blue battery icon; a completely charged battery is indicated with a lightning bolt overlaid on a green battery icon when the device is kept in the charger (See Figure 2.5).

Note

Using the device when it is in red battery status is strongly discouraged.

Batteries should be recycled or disposed of in accordance with local ordinances in force in your area.

Printer Maintenance

The optional Seiko™ thermal printer is shipped with its own user’s manual. Please refer to it for instructions as to loading paper, general use and safety.

Appendix A — Troubleshooting

Issue	Possible Reason	Solution
Device will not turn on	Using incorrect power supply	Use only power supply provided with pupillometer. Check label on power supply
Device will not turn on	Power cord is not fully plugged into the wall or the charging station	Check connections
Device will not turn on	Battery not installed correctly in device	Remove and replace following instructions in Instructions for Use (IFU)
Device will not turn on	Battery completely discharged	Verify that battery is installed correctly into the device. Charge the battery by positioning the pupillometer into the charger (see instructions in IFU)
Battery will not charge	Device is not placed in charging station correctly	Make sure to push device straight down into the charging station following instructions in the IFU and that a lightning bolt symbol is displayed on the battery icon
Targeting phase will not initiate after pressing the RIGHT or LEFT key	The headrest is not mounted on the pupillometer	Make sure to properly attach the headrest as indicated in the IFU
Pupil measurement will not initiate after release of the RIGHT or LEFT key	Too much blinking or heavy makeup	Gently hold patient's eye open with your finger during measurement

Issue	Possible Reason	Solution
Pupil measurement will not initiate after release of the RIGHT or LEFT key	Device not held correctly	Hold device at a 90-degree angle to patient's face. Make sure patient's eye is centered on the screen
The variables are displayed in red font on the measurement results screen	Device was removed from the eye too early	Hold device in place during the measurement phase until a text message on the screen reads "Measurement Done!"
The variables are displayed in red font on the measurement results screen	Excessive blinking	Gently hold the patient's eyelid open and repeat the measurement
The variables are displayed in red font on the measurement results screen	Excessive movement of user's hand or patient's head	Repeat the measurement
Record will not print	Pupillometer held too far away from printer or not in line of sight of IR window of printer	Printer must be held in direct line of sight of the infrared port in the pupillometer. See instructions in IFU
Record will not print	Measurement to print is not shown in the active screen	Browse to find record to print, then follow instructions in IFU
Video will not play	Pupil video record not present in memory	Perform and complete a pupil measurement
Patient ID number is not displayed	"Enter" key on screen keyboard not pressed after entering Patient ID	Select and press "Enter" on screen keyboard after entering patient ID number

Appendix B — Contact & Ordering Information

The following **options and accessories** can be ordered from NeurOptics:

NPi™-100	NeurOptics Pupillometer – US
NEUR-PWR1-BL	Pupillometer Charging Station Power Supply – US
NPi-CHG-01	NeurOptics Pupillometer Charging Station
BATPUP-01	NeurOptics Pupillometer Rechargeable Battery
NPi100-HR	NeurOptics Pupillometer Headrests (24-pack box)
NEUR-PRTS445	Seiko™ Printer
NEUR-PRTPSUS	Seiko™ Printer Power Supply – US
NEUR-PRTCBUS	Seiko™ US Printer Cable
49006	Seiko™ Printer Paper
NEUR-CASE-02	NeurOptics® Pupillometer Carrying Case
NEUR-2020-01	NPi Touch Screen Stylus

For more information, please contact NeurOptics or visit
www.NeurOptics.com

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18101 Von Karman Avenue, Suite 1940
Irvine, CA 92612
USA
Tel: +1 949.250.9792 or 866.99.PUPIL
Fax: +1 949.250.9796
info@NeurOptics.com
NeurOptics.com

Appendix C
Clinical Phenomena Affecting Pupillary Measurement

Vertex Variation:

The distance of the corneal apex to the first optical surface of an instrument is referred to as the “vertex distance”. Natural biological variation in the general population results in an anatomical vertex distance range of approximately 12 mm.

For modern pupillometers which are used in close proximity to the eye, this 12 mm variation can account for a significant fraction of the object distance to the eye. Therefore, the projected scale of a pupillometer which has not been adjusted for vertex distance may result in a significant measurement error of pupil size. To compensate for potential differences in vertex distances, the NeurOptics Pupillometer utilizes the NeurOptics VIP™ (Vertex Invariant Pupillometry™) technology, which reduces or eliminates the impact of vertex distance on pupillometry measurements.

Appendix D — Specifications:

NeurOptics Pupillometer - Model # NPi™-100

Measurement Characteristic	Input:	Human pupil size varying from 1 mm-9 mm.
	Output:	NPi™ (Neurological Pupil index™) Max and Min diameter, latency, average and maximum constriction velocity, average dilation velocity
	Accuracy:	± 0.03mm
Type of protection against electric shock	See Battery Charger (Class II)	
Degree of protection against Electric Shock	Pupillometer Headrest – Type BF Applied Part provided protection.	
Classification of the equipment against ingress of liquids	Ordinary equipment	
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	The equipment is not an AP or APG category equipment	
Mode of Operation	On Demand battery operation	
Power Supply:	3.7V 1800mAmp/hour Li: Ion Cell (battery)	
Operating Environment:	Temperature Range:	18°C (65°F) to 30°C(86°F)
	Relative Humidity:	20 % to 70 % RH. Non-condensing at all times
Transportation and Storage Environment:	Temperature:	0°C (32°F) to 75°C (167°F)
	Relative Humidity:	10 % to 95 % RH Non-condensing at all times
Dimensions:	With Headrest: 7.5” (191 mm) x 2.65” (67 mm) x 4.65” (118 mm)	
	Without Headrest: 7.5” (191 mm) x 2.65” (67 mm) x 3.65” (93 mm)	
Weight:	356 g ± 10g	
Classification:	Class 1 LED product per IEC 60825	

Accessories

NeurOptics Charging Station - Model # NPi-CHG-01	
Degree of protection	Type B Applied Equipment
Type of protection against electric shock	Class II Battery Charger
Classification of the equipment against ingress of liquids	Ordinary equipment
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	The equipment is not an AP or APG category equipment
Mode of Operation	Continuous operation
Power Supply:	Input: 100-240 VAC ± 8%
Power Line Frequency:	50/60 Hz

Seiko™ thermal printer **Model# NEUR-PRTE445**	Optional. See separate owners manual for instructions.

Returned Goods Policy

Products must be returned in unopened packages, with manufacturer's seals intact, to be accepted for replacement or credit, unless returned due to a complaint of product defect or mislabeling. Determination of a product defect or mislabeling will be made by NeurOptics, which determination will be final. Products will not be accepted for replacement or credit if they have been in the possession of the customer for more than thirty (30) days.